

### Remarks

Applicants have herein amended claims 1-2, 9-10, 23 and 40 to include proper antecedent basis, to recite the entire phrase for acronyms/abbreviations at each first occurrence, and to correct two minor typographical errors (*i.e.* the previously deleted letter "C" from "CMP-SA" in claim 2, and the previously deleted word "claim" preceding the number "26" in dependent claim 40). No new matter has been added.

Applicants have added new claims 48-55 to expand the embodiments of the elected subject matter. New claims 48-55 are drawn to the subject matter encompassed by the claims currently restricted to group I (see discussion below). Support for new claims 48-55 can be found in the specification as originally filed. In particular, support may be found in the specification, for example, at: page 19, paragraphs [0184]-[0185] (insect cells, *Spodoptera frugiperda*, *Tricoplusia ni*, *Estigmena acrea*, *Drosophila*); page 13, paragraph [0163] (yeast cells, plant cells, bacterial cells, fungal cells); and, pages 94-95, paragraphs [0392]-[0394] (CMP-Neu5Ac, CMP-KDN). No new matter has been added.

### Provisional Election

The Office Action mailed July 3, 2002 has required election of a subset of the currently pending claims, based on restriction of the claims into one of six different groups. *See*, Paper No. 12, page 2.

Applicants respectfully traverse the pending restriction requirement. Even assuming *arguendo* that a restriction requirement was proper, Applicants disagree with the claim composition as set forth in the present restriction requirement. In particular, claims 1, 2, 5, 26, and 44 are generic linking claims. *See*, M.P.E.P. § 806.04. And, as generic linking claims, generic claim 1 encompasses the subject matter of claim 25, generic claim 2 encompasses the subject matter of claims 3-4, generic claim 5 encompasses the subject matter of species claims 6-24 and 44; generic claim 26 encompasses the subject matter of species claims 27-43 and 47; and, generic claim 44 encompasses the subject matter of species claim 45. Furthermore, claims 5-24 & 46 are linked with claims 26-45 & 47 as product and process of using claims. *See*, MPEP § 809.03. Accordingly, Applicants submit that, at the very least, claims 5-24 and 26-47 should be regrouped a single set for examination purposes. Hence, at the very most, there should be no more than three restriction groups (as represented by [I] claims 1 and 25; [II] claims 2-4; and, [III] claims 5-24 and 26-47). Applicants

therefore respectfully request that, at the very least, the restriction requirement be redrawn for examination purposes into no more than three groups.

Furthermore, even where two patentably distinct inventions appear in a single application, restriction remains improper *unless* it can be shown that the search and examination of both inventions would entail a "serious burden" (*See* M.P.E.P. § 803). In the present situation, no such showing has been made. And even assuming, *arguendo*, that groups I-VI represent distinct inventions, Applicants submit that to search and examine the subject matter of these claims together would not be a serious burden. Accordingly, a search of claims 1, 2, and 5 would in fact provide all of the necessary information for consideration of the remaining claims. Applicants submit that a search of just these three claims would not present a serious burden and, therefore, respectfully request that the restriction requirement under 35 U.S.C § 121 be reconsidered and withdrawn.


Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144 should it be made final.

#### Conclusion

Applicants respectfully request that the above remarks be made of record in the file history of the instant application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 that is not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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In re Patent Application of:  
Betenbaugh, et al.

Application No.: 09/930,440

Group Art Unit: 1652

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For: Engineering Intracellular  
Sialylation Pathways

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**Version With Markings To Show Changes Made**

(underline = text inserted, ~~strike-through~~ = text deleted)

**In the claims:**

New claims 48-55 have been added.

Claims 1-2, 9-10, 23, and 40 have been amended as shown below:

1. A cell of interest producing a ~~the~~ donor substrate CMP-SA (cytidine monophosphate-sialic acid) above endogenous levels.
2. A cell of interest producing an acceptor substrate, the donor substrate CMP-SA ~~MP-SA~~, and expressing the enzyme sialyltransferase; wherein said acceptor substrate is a glycan.
9. The cell of claim 5, wherein said mammalian glycoprotein is selected from the group consisting of plasminogen; transferrin; Na<sup>+</sup>, K<sup>+</sup>-ATPase; and, thyrotropin ~~plasminogen, transferrin, Na<sup>+</sup>, K<sup>+</sup>-ATPase, and thyrotropin.~~
10. The cell of claim 5, wherein said cell expresses at least one enzyme selected from the group consisting of:
  - a) GlcNAc-2 epimerase (N-acetylglucosamine epimerase-2);
  - b) an enzyme catalyzing conversion of UDP-GlcNAc (uridine diphosphate-N-acetylglucosamine) to ManNAc (N-acetylmannosamine);

- c) sialic acid synthetase;
- d) aldolase;
- e) CMP-SA synthetase; and,
- f) CMP-SA transporter, ~~and~~

wherein said expression is above endogenous levels.

23. The cell of claim 10 wherein said cell further expresses at least one enzyme selected from the group consisting of:

- a) Gal T (Galactose Transferase);
- b) GlcNAc TI (N-AcetylGlucosamine Transferase I);
- c) GlcNAc TII (N-AcetylGlucosamine Transferase II); and,
- d) sialyltransferase, ~~and~~

wherein said expression is above endogenous levels.

40. The method of claim 26, further comprising suppressing activity of endogenous N-acetylglucosaminidase.